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SECTION 5 - 510(k) Summary

K121580

510(k) Summary Preparation Date: SEP 25 2012

1. 510(K) Owner:
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2. 510(k) Contact:
   Gerald S. Palecki
   Quality / Regulatory Consultant
   Palecki Enterprises LLP
   1107 259th ST NW
   Stanwood, WA 98292
   760-715-5954
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3. Device Trade Name: SureLase

   Common Name: CO_2 Laser System

   Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810).

   "A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide."

   Classification: Class II

   Product Code: GEX

4. Predicate Device(s)

   The SureLase CO_2 Laser System is equivalent in operating principles and intended uses to the Luxar LX-20SP and DEKA SmartXide CO_2 Laser Systems.

5. Device Description and Function

   The Clinicon SureLase laser system is a mobile platform that utilizes a radio frequency (RF) excited carbon dioxide (CO_2) laser tube to produce an infrared beam at a nominal 10.6 µm wavelength at powers adjustable from 2 to 20 Watts Continuous Wave (CW). Laser energy is conducted to the point of application by a flexible fiber waveguide and handpiece / tip assembly. Laser system operation is controlled by operator input on a touch-screen display panel. The RF laser drive is modulated to provide additional pulsed and superpulse emission modes selected from the laser system control panel.

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A "calibration port" on the side of the laser system allows checking and setting the power emitted from the distal laser aperture and serves as a check on fiber waveguide transmission efficiency. Laser system power, rates, and durations are adjustable as tabulated below:

Parameter	SureLase
CW Power (watts)	2 – 20
Pulsed Power (watts)	2 – 20
Gated Pulse Width (msec)	5 – 500
Gated Rep Rate (pps)	1 or 2 – 20
Superpulse Power (watts)	2 – 10
Gated Pulse Widths (msec)	10 – 500
Superpulse Pulse Rates (pps)	160 – 375
Gated Rep Rate (pps)	1 or 2 – 30
Peak Power (watts)	> 50
Superpulse Pulse Width (µsec)	100 -800

The laser system has safety features complying with requirements in 21 CFR 1040, Performance Standards for Light Emitting Products; IEC 60601-2-22, Medical electrical equipment –Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment ; and IEC 60825-1, Safety of laser products –Part 1: Equipment classification and requirements. Major safety features are as follows:

System On-Off Keyswitch, Emergency Stop Switch, Remote Interlock, Fiber Interlock, Beam Blocking Shutter, Internal Laser Power Detector, RF Power Monitor, and required Laser Safety Labels and Labeling.

The laser system, components, and features are illustrated in Figure 1. Laser system physical characteristics are:

Parameter	SureLase
Dimensions	40" H x 15" W x 15" D
Weight (Pounds / Kg)	~ 47 / ~ 21.3
Electrical Power	115 VAC, 15 A, 50/60 Hz

Delivery System: Flexible Fiber Waveguide; ~ 0.5mm ID.; Handpiece w/collet grip; waveguide tips.

Purge Gas: Provision for external air or inert gas purge through the Fiber and Handpiece / Tip.

System Cooling: Air; two thermostatically controlled fans with over-temperature protection.

Mobility: 4 wheels and handgrip on console for convenient system positioning.

6. Intended use(s) of the Device

The Clinicon SureLase CO_2 Laser System is intended for use in laser surgery procedures for incision, excision, vaporization, ablation, coagulation, or cauterization of soft tissue in specialties such as: general surgery, cosmetic surgery, dermatology, gynecology, head & neck surgery, neurosurgery, oral surgery, otorhinolaryngology, pediatric surgery, plastic & reconstructive surgery, podiatry, and urology.

7. Technological Characteristics Comparison to Predicate Devices

The technological characteristics comparison to predicate devices is summarized in the following table.

Characteristic	Clinicon Surelase	Luxar LX-20 SP	DEKA SmartXide
Predicate 510(k)	N/A	K953074	K072159
Laser Medium	CO_2	CO_2	CO_2
Wavelength (µm)	10.6	10.6	10.6
Laser Drive Source	RF	RF	DC
Output Power (W)	2 – 20	2 – 20	2 – 30
Pulsed Power (W)	2 – 20	2 -20	0.5 – 15
Gated PW (ms)	5 – 500	5 – 500	0.2 - 80
Gated Rep. Rate (pps)	1 or 2 – 20	2 -20	5 - 100
Super Pulse (W)	2 – 10	2 -10	0.5 - 10
Super Pulse Peak (W)	> 50	50	320
Beam Delivery System	Flexible Fiber Waveguide	Articulated Arm or Flexible Fiber Waveguide	Articulated Arm
System HxWxD (in)	40 x 15 x 15	36 x 14 x 14	47 x 19 x 22

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System Weight (lb)	47	42	66
Mobility	4 Wheels & Handle	4 Wheels & Handle	4 Wheels & Handle
Electrical Power	115 VAC	115 VAC	115 VAC
Intended Use	Incision, Excision, Vaporization, Ablation, Coagulation, or Cauterization of Soft Tissue	Incision, Excision, Vaporization, Ablation, Coagulation, or Cauterization of Soft Tissue	Incision, Excision, Vaporization, Ablation, Coagulation, or Cauterization of Soft Tissue

8. Performance Testing

   The SureLase CO_2 Laser System has been evaluated for performance equivalent to predicate devices through a combination of (1) verification and validation tests per product requirements and specifications and (2) inspections and tests derived from applicable regulations and safety standards as noted below.

   21 CFR 1040, Performance Standards for Light-emitting Products

   IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

   IEC 60601-2-22, Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

   IEC 60825-1, Safety of laser products – Part 1: Equipment classification, requirements and user's guide

9. Animal and Clinical Testing

   Device performance evaluation did not involve Animal of Clinical Testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Clinicon Corporation
% Palecki Enterprise, LLP
Mr. Gerald S. Palecki
Quality/Regulatory Consultant
1107 259TH Street NW
Stanwood, Washington 98292

SEP 25 2012

Re: K121580
Trade/Device Name: SureLase CO_2 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 8, 2012
Received: August 14, 2012

Dear Mr. Palecki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - Indications for Use

510(k) Number (if known): K121580

Device Name: SureLase CO_2 Laser System

Indications for Use:

The Clinicon SureLase CO_2 Laser System is intended for use in laser surgery procedures for incision, excision, vaporization, ablation, coagulation, or cauterization in specialties such as: general surgery, cosmetic surgery, dermatology, gynecology, head & neck surgery, neurosurgery, oral surgery, otorhinolaryngology, pediatric surgery, plastic & reconstructive surgery, podiatry, and urology.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of Surgical, Orthopedic, and Restorative Devices

510(k) K121580